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*Application No. 10/603297*  
*Page 6**Amendment*  
*Attorney Docket No. S63.2N-11064-US01***Remarks**

This Amendment is in response to the Office Action dated August 18, 2006.

Applicants have amended the paragraph on page 1, lines 5-11 of the specification relating to the continuity data. Specifically, the attorney docket number, 760-46/CIP/PCT/USA/CON3, with the U.S. Patent Application Serial No. 10/375,780, now issued as U.S. patent No. 7,115,140. At the time of filing the present application, Applicants had only the attorney docket number, and not the U.S. Patent Application Serial number. No new matter has been added.

**Rejections****35 U.S.C. §112**

Claims 12 and 25 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action asserts that “[c]laims 12 and 25 recite the matrix being non-elastomeric and the fibers being elastomeric. However, there is no teaching in the specification for said limitation.”

Applicants have amended claim 12. Support for the amendment to claim 12 is found at least from claim 10 of WO 95/33422 (PCT/1B95/00492) as filed, the entire content of which was incorporated by reference on page 1 of the current specification. The present application is a continuation of U.S. Patent No. 7,115,140 which is a continuation of U.S. Patent Application Serial No. 09/711,034 filed November 13, 2000 which is a continuation of WO 95/33422 (PCT/1B95/00492) filed June 6, 1995, designating the U.S., U.S. National Stage application No. 08/591,506. Claim 10 was part of the original specification as filed and therefore, the subject matter claimed therein is not new matter. Applicants have amended the specification at page 11, lines 25 accordingly.

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Applicants traverse the rejection with respect to claim 25. Support for claim 25 is found at least from claim 12 of WO 95/33422 (PCT/IB95/00492) as filed.

No new matter has been added.

Claim 27 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action asserts that “[t]he Applicant is required to clarify to what the claim is intended to be drawn to, i.e. either the catheter alone or the combination of the catheter and the stent.”

Applicants have amended claim 27 to properly depend from claim 15. This was an inadvertent error. Applicants have also amended claim 15 so that the language is consistent in referring to a “stent member”, rather than a stent. No new matter has been added.

Applicants respectfully request withdrawal of the rejection of claims 12, 25 under 35 U.S.C. §112, first paragraph, and request withdrawal of the rejection of claim 27 under 35 U.S.C. §112, second paragraph.

#### *35 U.S.C. §102*

Claims 1-4, 6-11, 14, 16-18 and 20-24 have been rejected under 35 U.S.C. §102(e) as being anticipated by US 5,201,706 to Noguchi et al.

Applicants have amended claim 1 to incorporate the limitations of claim 4. No new matter has been added.

Claim 1, as amended, is directed to a balloon comprising fibers embedded in the matrix material of the balloon.

Applicants submit that Noguchi et al. discloses a balloon catheter reinforced with

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a composite fiber consisting of an elastic yarn and a non-elastic yarn. See col. 1, lines 57-60.

The balloon consists of a three-layered structure of an outer elastic film 10, a cylindrical body 12 of a composite yarn and an inner elastic film 14, *each of which is a distinctive layer which is separable from the other layers.* See FIG. 1, col. 3, lines 10-14.

Consequently, claim 1 as amended is not anticipated by Noguchi et al. because the cylindrical body of composite yarn disclosed by Noguchi et al., is not embedded in a balloon matrix material as recited in amended claim 1.

Claims 2, 3 and 5-13 depend from claim 1 and not anticipated by Noguchi et al. for at least the reasons that claim 1 is not anticipated by Noguchi et al.

Independent claim 14 has been amended to incorporate the limitations of claim 18, and is now directed to “[a] catheter system...having an inflatable portion comprising a matrix material and fibers embedded in the matrix material....”

Claim 14 is not anticipated by Noguchi et al. for at least the reasons that claim 1 is not anticipated by Noguchi et al.

Claim 19 has been amended to depend from claim 14 and to correct a typographical error. Claim 19 inadvertently failed to recite which claim it was dependent from and the words “wherein said” were inadvertently omitted from the claim. No new matter has been added.

Claims 15-17 and 19-27 depend from claim 14 and is not anticipated by Noguchi et al. for at least the reasons that claim 14 is not anticipated by Noguchi et al.

Applicants respectfully request withdrawal of the rejection of claim 1-3, 5-17 and 19-27 under 35 U.S.C. §102(e) as being anticipated by Noguchi et al., U.S. 5,201,706.

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**35. U.S.C. §103**

**Claims 5 and 19**

Claims 5 and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Noguchi et al. in view of UK 1,566,674 to Hanecka et al. The Office Action asserts that "Noguchi teaches a fabric fiber body but is silent with regards to the orientation of the fabric body having a helical pattern. However, Hanecka teaches a similar reinforced balloon catheter having a fabric body formed with a helical pattern (page 2, line 117)."

Claim 5 depends from claim 1 and claim 19 depends from claim 14.

Claims 1 and 14 have been amended and are distinguished over Noguchi et al. as discussed above.

Hanecka discloses a bulb catheter formed by a portion of an outer tube, enlarged by expansion which is slid with relatively slight clearance over an inner tube. See page 1, lines 40-50:

To prevent irregular and unlimited extension of the bulb in dependence on the external resistance, the bulb, which can be stretched by relative displacement of the tubes as they are pushed one inside the other, can be reinforced by means of a fabric, more particularly, a synthetic fibre fabric.

Page 2, lines 32-40.

Again, Hanecka, like Noguchi et al., discloses a layered structure, each layer of which can be distinguished from another.

Consequently, combining Hanecka with Noguchi et al., fails to suggest the invention of either claim 1 or claim 14 as amended, wherein the fibers are embedded within the matrix material of the balloon (claim 1) or expandable member of the catheter system (claim 14), as neither reference discloses nor suggests this feature.

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Claim 5 depends from claim 1 and claim 19 depends from claim 14. Claims 5 and 19 are patentable over Noguchi et al. in view of Hanecka for at least the reasons that claims 1 and 14 are patentable over Noguchi et al. in view of Hanecka respectively.

Applicants respectfully request withdrawal of the rejection of claims 5 and 19 under 35 U.S.C. §103(a) as being unpatentable over Noguchi et al. in view of UK 1,566,674 to Hanecka et al.

**Claims 12 and 25**

Claims 12 and 25 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Noguchi et al.

Claim 12 depends from claim 1 and claim 25 depends from claim 14.

Claims 1 and 14 have been amended and are patentable over Noguchi et al. for the reasons discussed above. Noguchi et al. fails to suggest fibers embedded in the matrix material of a balloon (claim 1) or expandable member (claim 14).

Claims 12 and 25 are patentable over Noguchi et al. for at least the reasons that claims 1 and 14 are patentable over Noguchi et al.

Applicant respectfully requests withdrawal of the rejection of claims 5 and 19 under 35 U.S.C. §103(a) as being unpatentable over Noguchi et al.

**Claims 13, 15, 25 and 27**

Claims 13, 15, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noguchi et al and in view of US 5,100,429 to Sinofsky. The Office Action asserts that "Noguchi teaches an inflatable balloon catheter capable of expanding a stent but is

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silent with regards to the combination of the catheter and the stent....Sinofsky teaches a stent 112 releasably attached or mounted by a bond (col. 9, lines 51-53) to an inflatable portion of a catheter 120...."

Claim 13 depends from claim 1.

Claims 15, 26 and 27 depend from claim 14.

Claims 1 and 14 have been discussed above and are distinguished over Noguchi et al. because Noguchi et al. fails to suggest *fibers embedded in a matrix material* of a balloon (claim 1) of expandable member of a catheter system (claim 14).

Combining the stent/catheter combination of Sinofsky fails to suggest a balloon or expandable member of a catheter system wherein fibers are embedded in the matrix material of the balloon or expandable member.

Claims 1 and 14 are therefore not suggested by this combination. Claims 13, 15, 26 and 27 are patentable over Noguchi et al. in view of Sinofsky at least for the reasons that claims 1 and 14 from which they depend, are patentable over Noguchi et al. in view of Sinofsky.

Applicants respectfully request withdrawal of the rejection of claims 13, 15, 26 and 27 under 35 U.S.C 103(a) as being unpatentable over Noguchi et al and in view of US 5,100,429 to Sinofsky.

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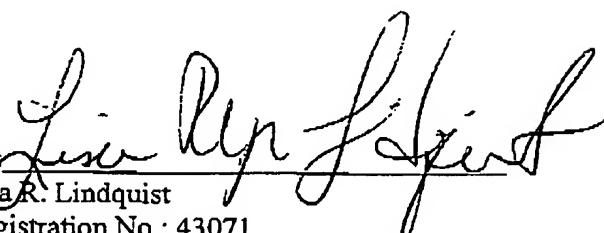
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## CONCLUSION

Claims 4 and 18 have been canceled. Claims 1-3, 5-17 and 19-27 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

VIDAS, ARRETT &amp; STEINKRAUS

Date: November 15, 2006By:   
Lisa R. Lindquist  
Registration No.: 43071

6109 Blue Circle Drive, Suite 2000  
Minnetonka, MN 55343-9185  
Telephone: (952) 563-3000  
Facsimile: (952) 563-3001

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